#	Topic	4068-P Provision	Final Rule Provision
B1	Auto-enrollment	We requested comments on: • Responsibility for auto-enrollment: Should CMS or the State perform the auto-enrollment function (or a contracted entity or entities on their behalf)? • Timing of auto-enrollment. • Auto-enrollment of MA-onlys: How to provide Part D to those full-benefit dual eligible individuals who are in an MA-only plan and who have failed to enroll in a PDP or MA-PD plan? • How to provide Part D to a full-benefit dual eligible individual enrolled in an MA-only plan when the premium for the MA-PD plan(s) offered by the same MA organization exceeds the low-income premium subsidy amount?	The proposed CMS response seeks to balance the twin goals of ensuring prescription drug coverage and respecting beneficiary choice. We: • will stipulate that CMS–not the states–will perform auto-enrollment; • will perform the auto-enrollment in the fall of 2005 as soon as eligible Part D plans are known, and auto-enrollment will be effective January 1, 2006. After 2006, full-benefit dual eligible individuals will be auto-enrolled into plans as soon as their Medicare Part D eligibility is determined; • will auto-enroll on a random basis among available PDPs; • will reserve the ability to conduct re-auto-enrollment if we find such action necessary to ensure adequate coverage for this population; • will facilitate full-benefit dual eligible individuals who are MA enrollees into the MA-PD with the lowest Part D premium, even if the premium is not covered by the low-income premium subsidy amount. • may facilitate enrollment for all others deemed or determined eligible for the low-income subsidy, i.e. Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), Qualifying Individuals (QI-1s) , and others who qualify for low income subsidies.
B2	Optional Involuntary Disenrollment for Disruptive Behavior	We solicited comments on the applicability of MA rules to PDPs for involuntary disenrollment for disruptive behavior.	CMS developed policy to permit PDP sponsors to disenroll individuals for disruptive behavior consistent with statutory intent, while creating the necessary due process safeguards for individuals who are subject to our disenrollment rules and may, as a result, lose Part D coverage. In the final rule, we • removed the expedited process; • required PDP sponsors to provide a reasonable accommodation as determined by CMS and in exceptional circumstances we deem necessary; and • reserved the right to deny a request from a fallback prescription drug plan to disenroll an individual for disruptive behavior.
B3	Enrollment and Disenrollment Processes	Paper Enrollment Form: We envisioned a paper enrollment form process and requested comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues.	We will maintain the flexibility to allow PDPs to develop alternative mechanisms other than paper enrollment forms. We will look to our recent experience with the drug card for other mechanisms we may consider, such as enrollment over the telephone and through the Internet. We will require plans to disenroll individuals upon receipt of notification

#	Topic	4068-P Provision	Final Rule Provision
		Disenrollment for Moving Outside Service Area: We asked if we should require PDPs to disenroll individuals if they no longer reside in the service area.	that they have moved outside of the plan service area.
B4	Release of Beneficiary Information for Marketing	Providing Beneficiary Information to Sponsors: Should we provide individual beneficiary information to Part D sponsors for marketing purposes because Part D is an entirely new, voluntary benefit that would not otherwise be available to beneficiaries absent positive enrollment?	We do not commit at this time to provide PDPs and MA-PDs with information. Since we do not need regulatory language to implement this provision, CMS will commit to consider provision of such information pending further research of the needs and capabilities of both organizations and CMS. If/when we do provide such information to PDPs and MA organizations, CMS will work with industry and advocates to develop appropriate guidance.
B5	Creditable Coverage	Creditable Coverage Notices Process: What should be the format, placement, and timing of creditable coverage notices? Other Forms of Creditable Coverage: Are there more forms of coverage that we should consider creditable coverage?	We support linking the notice of creditable status to other required documents as an acceptable vehicle provided it is conspicuous and includes standard information elements. This approach appropriately recognizes the importance and familiarity of materials that beneficiaries currently receive regarding coverage they have. Further, we believe that it is important to encourage compliance with the provision of these notices by eliminating duplication and the undue burden associated with it. To that end, we have revised §423.56(c) and (d) to allow notices of creditable and non-creditable status to be provided in the same manner, and will provide specific guidance following the publication of the rule. This guidance will require that a notice of creditable and non-creditable status be provided, at minimum, prominently with other beneficiary information materials, and will include model language for both types of notices. To ensure beneficiaries are making informed choices, we require that notice must be provided to all Part D eligible individuals prior to the commencement of the Annual Coordinated Election Period (AEP), which begins on November 15, 2005, and also prior to the AEP each year. We also believe there are three other key times when notice must be provided -- (1) prior to the commencement of the individual's initial enrollment period; (2) prior to the effective date of enrollment in such coverage and/or any change in creditable status of that coverage; and (3) upon request by the beneficiary. We will revise §423.56(f) to require that notice be provided, at minimum, at these 4 times. We will revise §423.56(b) to include section 1876 Cost plans and coverage offered by State high risk pools as well as a provision permitting CMS to recognize other types of coverage as potentially

#	Topic	4068-P Provision	Final Rule Provision
			creditable in guidance following publication of the final rule.
B6	Marketing multiple products	Given companies frequently offer additional products that could provide additional tools to help beneficiaries manage expenses and financial security, we asked for comments on allowing such products to be provided in conjunction with PDP services and the appropriate limitations on such activities.	We will allow only additional health-related products to be marketed to Medicare beneficiaries in compliance with HIPAA. Additional non-health related marketing of products would need written authorization by the beneficiary.
B7	Retroactive Eligibility	We did not raise the prospect of retroactive eligibility in the proposed rule This issue is closely linked to the precise meaning of "eligibility" for Part D. As described in the Part D NPRM, an individual is "eligible for Part D" when s/he is entitled to Part A and/or enrolled in Part B, and separately is "eligible to enroll in a Part D plan" when s/he satisfies the additional residency requirement. Defining eligibility for Part D in this way, independent of the additional requirements imposed by the Act in section 1851 for actually enrolling in a Part D plan, creates the untenable position of determining an individual as "eligible" for participation but not providing an avenue to actually participate. MA eligibility is predicated upon entitlement to Parts A and B, residency in the plan's service area, making an enrollment election and agreeing to abide by the rules of the MA plan. Consistent with section 1851(f) of the Act, we do not provide for a general retroactive MA enrollment process.	We do not believe that eligibility for Part D should be retroactive. An important consideration is that a State's ability to furnish Medicaid drug coverage to individuals with Medicare ends when an individual becomes eligible for Part D, therefore an individual who is retroactively eligible for Part D would lose his or her Medicaid coverage for that period. Further, providing retroactive enrollment in a Part D plan would have many practical and operational complications. We will define eligibility for Part D as we have for MA; as a sum of the parts that together equal an individual's ability to enroll in a Part D plan and establish prospective enrollment requirements, thereby preventing retroactive eligibility.
C1	Incurred Costs (TrOOP)	TrOOP Exclusion Definitions: How should we define group health plan (GHP), insurance or otherwise, and other third party arrangements for purposes of TrOOP? Treatment of HSAs (FSA, HRA, MSA) under TrOOP: Can we treat HSAs, FSAs, and MSAs as beneficiary money, and HRAs, as GHP? Level playing field between mail-order and network pharmacies: Should the price differential between the cost	OGC was able to craft definitions in § 423.100 that are consistent with our goals of defining "payments made by a beneficiary or another person on their behalf" as broadly as possible , while maintaining the integrity of the exclusions of 'group health plan, insurance or otherwise, and other third party arrangements' intended in the statute. We will allow beneficiary payment differentials to count toward TrOOP in cases in which a beneficiary accesses a covered Part D drug consistent

#	Topic	4068-P Provision	Final Rule Provision
		of an extended supply of a drug purchased at a retail pharmacy versus a mail-order pharmacy be counted as an incurred cost against the annual out-of-pocket threshold?	with the out-of-network policy in §423.124(a) of our final rule, and when a beneficiary purchases an extended supply of covered Part D drugs at a retail rather than a mail-order pharmacy. Our definition of the term "incurred costs," at §423.100 of our final rule will therefore remain unchanged.
		Financial Assistance from Pharmacies and Drug Manufacturers: Clarification of status of financial assistance and free goods and services from PhRMA under the anti-kickback provisions? (1128A(a)(5), 1128A(i)(6)).	Regardless of whether a manufacturer patient assistance program is a bona fide charity for the purpose of Federal fraud and abuse laws, any drug payments it makes on behalf of Part D enrollees would count toward TrOOP unless these organizations qualify as group health plans, insurance or otherwise, or similar third-party payment arrangements. However, any arrangements pursuant to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with Federal fraud and abuse laws, where applicable, including the anti-kickback statute at section 1128(b) of the Act, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the Act.
		A related issue - although it was not mentioned in the proposed rule -- is whether pharmacies can waive or reduce Part D cost-sharing obligations given Federal fraud and abuse laws and, if they can, whether such waived or reduced cost-sharing should count toward a beneficiary's TrOOP limit.	Under the new exception to the Anti-Kickback Statute added by section 101(e) of the MMA, pharmacies are permitted to waive or reduce cost-sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts, as set forth in section 1128A(i)(6)(a) of the Act. In addition, a pharmacy may waive or reduce a beneficiary's part D cost-sharing without regard to these standards for beneficiaries enrolled in a prescription drug plan or Medicare Advantage plan eligible for the low-income subsidy under section 1860D-14 of the Act, provided the pharmacy has not advertised that such waivers or reductions of cost-sharing are available. Pharmacies that waive or reduce cost-sharing amounts for covered part D drugs without following the requirements of the pharmacy waiver safe harbor could be subject to civil monetary penalties, including fines and exclusion from participating in federal health care programs, as well as criminal fines and imprisonment under the Anti-Kickback Statute. We will allow waivers or reductions of Part D cost-sharing by pharmacies to count toward TrOOP. Not allowing such waived or reduced cost-sharing to count toward TrOOP would present systems

#	Topic	4068-P Provision	Final Rule Provision
			difficulties for plans given the need to track down whether cost-sharing was actually incurred by a beneficiary rather than a pharmacy. Having initially been charged the cost-sharing amounts for covered part D drugs, the beneficiary arguably incurred such costs - even if the pharmacy elects not to collect those amounts. Moreover, we believe this option is consistent both with the definition of "person" in the proposed rule (making waiver or reduction of cost-sharing applicable toward an enrollee's incurred costs), and with Congressional intent in amending the Anti-Kickback Statute to provide for a pharmacy safe harbor.
C2	Dispensing Fee	Dispensing Fees: We invited comments on three definitions of "dispensing fees": Option 1: only those activities related to the transfer of possession of the Part D drug from the pharmacy to the beneficiary, including charges for mixing drugs, delivery, and overhead. Option 2: the activities included in Option 1, as well as amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered. Option 3: the activities in Option 2, as well as activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.	We will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead (Option 1). This is consistent with the consensus of the pharmacy community that dispensing fees for routine prescriptions should include costs associated with the filling of a prescription and transfer of possession to the patient (plus a reasonable profit). The other options would have included supplies, equipment, and professional services that are not typically included in dispensing fees but, rather, are typically paid through a separate fee or additional compensation.
C3	Covered Part D drug definition	Part B/D Issues: We solicited comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined "Part D & B" coverage package. Exclusion for tying arrangements: We are concerned that the exclusion of outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer (or its designee) as a condition of sale may be too narrow to address inappropriate tying arrangements. We may consider expanding this exclusion and solicit public comments on how to reduce the risk of abusive tying arrangements.	We identify issues and discuss coverage of the following with respect to the definition of Part D drug: • Vaccines • Compounded Drugs • Parenteral Nutrition • Insulin Supplies • Exclusion of A/B Drugs if individual could have enrolled in A or B. • Tying Arrangements

#	Topic	4068-P Provision	Final Rule Provision
C4	LTC Pharmacies	Definition of LTC Facility: We request comments regarding our definition of the term long-term care facility in § 422.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in § 440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals.	We have expanded the definition of the term "long-term care facility" in §423.100 of our final rule to encompass not only skilled nursing facilities, as defined in section 1819(a) of the Act, but also any medical institution or nursing facility for which payment is made for institutionalized individuals under Medicaid, as defined in section 1902(q)(1)(B) of the Act. We note that we have eliminated the reference to nursing facilities as defined in section 1919(a) of the Act, as such facilities are incorporated captures as nursing facilities for which payment is made for institutionalized individuals under Medicaid. Such an expansion would include ICF/MRs and inpatient psychiatric hospitals – along with skilled nursing and nursing facilities – in the definition of a long-term care facility, provided those facilities meet the requirements of a medical institution that receives Medicaid payments for institutionalized individuals under section 1902(q)(1)(B) of the Act. We do not believe that the definition of term long-term care facility should be expanded to include other facilities recognized by State law but not by Medicare or Medicaid, regardless of whether some of these facilities contract on an exclusive basis with long-term care pharmacies. Furthermore, we do not believe that our definitions of terms associated with institutionalized Part D enrollees should conflict.
		How should we guarantee "convenient access" to the pharmacy benefit for Part D enrollees who reside in LTC facilities? We welcomed comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.	We are adopting an approach requiring Part D plans to demonstrate "convenient access" to in-network LTC pharmacies that will inject competition into the LTC pharmacy market, but also allow the option of maintaining the relationships and levels of service that LTC facilities now enjoy vis-à-vis their contracted LTC pharmacies. This approach involves the use of our authority under section 1860D-4(b)(1)(C)(iv) of the Act to establish an "any willing pharmacy" requirement for LTC pharmacies, coupled with a requirement that plans develop standard contracting terms and conditions for LTC pharmacies. Any pharmacy in a service area could become an eligible LTC pharmacy by certifying that they meet certain packaging, service and delivery requirements and standards for LTC pharmacies as specified by us in separate guidance. We will require plans to demonstrate (in their applications) "convenient in-network access" to LTC pharmacies by means of standard AWP contracts for LTC pharmacies to inject competition into the LTC pharmacy market. We believe this option aligns incentives to accomplish several goals: (1) assuring that LTC pharmacies come to the

#	Topic	4068-P Provision	Final Rule Provision
			table in good faith; (2) negotiation of potentially more competitive pricing than currently exists in the LTC pharmacy market; (3) allowing for the one LTC facility-one LTC pharmacy to remain intact, to the extent that LTC facilities would like to keep it that way; and (4) lowering overall costs for plans, enrollees, and the Medicare program.
C5	Network Access Standards – Home Infusion	In the NPRM preamble, we stated that we are considering using the authority in Section 1860D-4(b)(1)(C) of the Act (which establishes requirements regarding convenient access to network pharmacies) to require that plans contract with a sufficient number of home infusion pharmacies in their service areas to provide reasonable access for Part D enrollees, as stand-alone drug plans may not have an incentive to include home infusion pharmacies in their networks. Should we use the authority in section 1860D-4(b)(1)(C) of the Act to require that both MA-PD plans and PDPs contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees? How could such a requirement be structured?	Given coverage of home infusion drugs under Part D, we do not believe it is an option for plans not to include at least some home infusion pharmacies in their network in order to provide enrollees with meaningful access to those drugs. We believe that safe and appropriate access to such drugs in the home environment is only possible through the use of specialized home infusion pharmacies. However, we do not think it is reasonable to require plans to include all home infusion pharmacies in networks. We will require plans to provide adequate access to home infusion pharmacies but will not specify what we mean by adequate access in the final rule. Plans will be required to tell us how they would provide such access in their service area. This approach will provide plans with flexibility to meet the standard in any of a number of ways, and it will not obligate us to specify what is meant by "adequate access".
C6	Network Access Standards – Tricare Standards (Retail)	In the NPRM preamble, we proposed applying these access standards such that a PDP or regional MA-PD plan would have to meet or exceed the access standards across each region in which it operates, and a local MA-PD plan would have to meet or exceed the access in its local service area.	We will require plans to meet the TRICARE access standards at the state level, and will include a provision in the final rule that gives us the flexibility to establish an exceptions process in states in which it is impossible or impracticable to meet the access standards – particularly with respect to rural areas. This seems to be a reasonable compromise between application of the standard at the local level and application at the regional or national level.
C7	Network Access Standards – Non-Retail	Should we allow plans to count certain non-retail pharmacies, such as I/T/U pharmacies and pharmacies operated by FQHCs and Rural Health Centers (RHCs), toward the pharmacy access standards in some (or all) cases? We also solicited comments on permissible ways to ensure Part D enrollees' access to FQHC and rural pharmacies, etc.?	We will allow plans to count I/T/U pharmacies and other rural institutional pharmacies (e.g., FQHCs, RHCs) toward the pharmacy access requirements in all cases, provided such pharmacies are under contract with the plan. We believe such a policy would create incentives for plans to contract with pharmacies serving populations in rural areas. However, in order for access to retail pharmacies in rural areas not be curtailed, we must review plans' proposed plan networks to ensure that their inclusion of I/T/Us, FQHCs, and RHCs does not substitute for the inclusion of retail pharmacies in any areas.

#	Topic	4068-P Provision	Final Rule Provision
C8	Network Access – I/T/U Pharmacies	We asked: How will I/T/U pharmacies and IHS beneficiaries achieve maximum participation in Part D benefits**?** What are the advantages and disadvantages for AI/AN enrollees who are eligible to enroll in Part D: Option 1**:** If we use our authority under Section 1860D-4(b)(1)(C)(iv) of the Act to require that PDP sponsors and MA organizations approach any I/T/U pharmacies in their plan service areas with at least the same terms available under the plan's standard pharmacy contract. Option 2: If we do not require that plans contract with I/T/U pharmacies and, instead, strongly encourage PDP sponsors and MA organizations offering MA-PD plans to negotiate with and include I/T/U pharmacies in their plans' pharmacy networks?	Section 1860D-4(b)(1)(C)(iv) permits us to include standards for convenient access to covered Part D drugs for enrollees who obtain their prescription drugs at I/T/U pharmacies. Such pharmacies are unique due to statutory and regulatory requirements and other special circumstances. Many of these differences will require modifications to standard commercial contract provisions. We will require Part D plan sponsors to include I/T/U pharmacies in their networks to the extent that those pharmacies are present in their service areas. We will require that plans offer AWP contracts to I/T/U pharmacies that include an addendum addressing certain minimum terms and conditions specified by us in separate guidance. We will require Part D plans to demonstrate that they have contracts with a sufficient number of I/T/U pharmacies to ensure "convenient access" to prescription drugs for AI/AN enrollees within the service area.
C9	Any Willing Pharmacy	Should we require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks? Should "any willing provider" provisions apply to non-retail -- in particular mail order – pharmacies, as well as to retail?	We will require plans to offer standard terms and conditions to all pharmacies for purposes of ensuring that any pharmacy willing to accept the standard contact terms and conditions can join the pharmacy network. It is important to clarify that standard terms and conditions – particularly with respect to payment terms – may vary to accommodate geographic areas or types of pharmacies (e.g., long-term care pharmacies) and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. With standard terms and conditions as a "floor," plans may always modify terms and conditions in their standard terms and conditions to encourage participation by particular pharmacies. The any willing pharmacy statutory language is general enough to permit any pharmacy – including a non-retail pharmacy – that meets a plan's contracting terms and conditions to participate in that plan's network. A review of the legislative history related to this provision does not provide any additional guidance regarding whether the any willing pharmacy requirement at section 1860D-4(b)(1)(A) was intended to relate to any specific type of pharmacy – retail, mail-order, or otherwise. Given this assessment, we believe that the any willing pharmacist requirement applies to all pharmacies, notwithstanding a plan's ability to set up more restrictive networks (preferred pharmacies)

#	Topic	4068-P Provision	Final Rule Provision
			within its broader network.
C10	OON Access	How should emergency access standards work? It is doubtful that emergencies can be appropriately evaluated and authorized at the pharmacy. In the NPRM, we required plans to ensure that their enrollees have adequate access to drugs dispensed at OON pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. In addition, our proposed regulations specify that enrollees who access their drugs at an OON pharmacy must pay: (1) any cost-sharing, relative to the plan allowance for that covered Part D drug, that would have applied had the drug been obtained at a network pharmacy, and (2) the difference between the price charged by the OON pharmacy and the plan's negotiated price for that drug. We requested comments on our proposed out-of-network access requirements. OON Cost Sharing For Subsidy-Eligible Individuals: In the preamble to our proposed regulations, we specified that the case of a Part D enrollee who is residing in a long-term care facility whose long-term care pharmacy does not contract with that enrollee's MA-PD plan or prescription drug plan is one in which we would expect plans to provide out-of-network access to drugs as provided under section 423.124 of our regulations.	We adopt the OON access policy proposed in the NPRM and clarify that §423.124(c) of our final rules requires plans to establish reasonable rules to ensure that enrollees use out-of-network pharmacies in an appropriate manner (i.e., limiting the application of this policy to urgent and out-of-area situations; limiting the amount of covered Part D drugs dispensed at an OON pharmacy to a three- or five-day supply; requiring that a traveling beneficiary with a need for maintenance medications obtain an extended supply of those drugs via the plan's mail-order option; requiring pre-authorization for OON access (or, alternatively, plan notification for after-hours or "emergency" requests)) – provided they ensure adequate access to out-of-network pharmacies on a non-routine basis when enrollees cannot reasonably access network pharmacies. . We have defined the beneficiary cost sharing in relation to the total cost of the drug to the plan and the beneficiary. Therefore, in cases where the total payment is not limited by the plan allowable due to OON status, the cost sharing should be defined as the total paid by beneficiary, or in the case of a low-income individual, as the total cost sharing paid by both the beneficiary and CMS. This approach reconciles the need to both charge the OON differential and to hold the low-income beneficiary liable for only the statutorily allowed copayment amounts ($1/$3, or $2/$5).
C11	Formularies	We requested comments on many aspects of formulary management, such as: • Does requiring a formulary to be "developed and reviewed" by a P&T committee mean that a P&T committee's decisions regarding the plan's formulary must be binding on the plan? • Should we strengthen the statutory requirement in section 1860D-4(b)(3)(A)(ii) of the Act by requiring that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict?	We made changes to the regulatory formulary requirements to balance: (1) building specific requirements into regulatory language to ensure plans offer a comprehensive formulary; with (2) maintaining flexibility to fine-tune formulary review requirements via subregulatory guidance consistent with the final formulary review standards and processes developed by CMS based on public comment. The regulatory text revisions: • Clarify that P&T committee members must be independent and free of conflict with respect not just to plans, but also pharmaceutical manufacturers. • Specify a role for P&T committees in the approval of policies that guide medical exceptions and other utilization management

#	Topic	4068-P Provision	Final Rule Provision
		• Should we require the direct involvement of a Pharmacy and Therapeutics Committee with cost containment measures, as well as with other areas of quality assurance and medication therapy management? • What standards and criteria could we use to determine that a PDP sponsor or MA organization's formulary that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries? • How can we balance plans' flexibility to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees? • What should be the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA-PD plans (for example, quarterly, annually)?	processes, as well as treatment protocols and procedures related to a plan's formulary. • Require the provision of adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines – above and beyond the 2-drugs-per-category-and-class requirement. • Provide CMS with the flexibility to specify additional requirements regarding plans' P&T committees and formularies via subregulatory guidance. • Specify that CMS will review plan formularies consistent with the non-discrimination provisions at § 423.272(b)(2). CMS intends to conduct a comprehensive review of the plan design consistent with explicit formulary review standards and criteria-driven processes. State Medicaid programs and advocates for dual eligibles and beneficiaries with certain illnesses have expressed a great deal of concern about: (1) how we plan to handle the transition of dual eligibles and individuals whose conditions are stabilized on particular drugs – some of which may not be on plan formularies; and (2) more generally, the adequacy of plans' formularies for treating certain complex medical conditions. We are recommending a three-part strategy: (1) establish formulary review criteria that require plans to cover Part D drugs associated with certain diseases; (2) adopt a substantive rule requiring coverage of non-formulary drugs on appeal given medical necessity and determination is upheld upon review; and (3) require an appropriate transition policy for new enrollees.
D1	Quality Standards	Are there industry standards for cost effective drug utilization management and should CMS adopt any of these standards for PDPs and MA-PD plans? Among the issues we raised in the preamble is whether or not we should use the OBRA90 Medicaid standards for these programs. OBRA90 requires pharmacy programs to	We require plans to represent that their network providers are required to comply with pharmacy practice standards established by the states, to establish concurrent and retrospective DUR policies and systems, and to establish internal medication error identification and reduction systems. We are already working on E-prescribing and EMR standards. We can develop more detailed specifications in subsequent policy guidance if we determine that such is warranted.

#	Topic	4068-P Provision	Final Rule Provision
		use proDUR and retroDUR and to offer counseling services. There is some controversy in the research literature on the value of DUR, but they are generally accepted standard within the industry.	We will encourage and work with the private sector to develop: (1) additional standards, (2) methods for reporting adverse events and other quality measures to CMS, and (3) methods for PDPs to measure adverse events and perform quality assurance functions.
D2	MTMP	We sought comments on what requirements and/or guidelines for MTMPs should be formulated in our regulations. How should we provide guidance to drug plans in defining "multiple chronic diseases" and "multiple covered Part D drugs" for the purposes of determining which Part D enrollees would qualify for MTMP services, or are these determinations are best left to the plans as part of their benefit design? As both a policy and legal matter, should the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services be determined by the drug plan? What guidance could we provide to plans to ensure these services are targeted in the most efficient manner and to the most appropriate beneficiaries?	CMS received a significant volume of comments on MTM. Almost all the comments agreed that MTM can make a significant difference in improving therapeutic outcomes. However, the comments provided significant differences of opinion on what practices are necessary to achieve improved therapeutic outcomes and which beneficiaries will benefit most from MTM. Despite some best practice examples, no widely accepted MTM standards of practice were identified. In light of the lack of widely accepted standards of practice and the uncertainty as to how plans can reasonably and effectively implement MTM programs under the Medicare Prescription Drug Benefit, we will not specify further service and service level requirements at this time. We also will not specify multiple chronic diseases and multiple drug requirements, but must establish the cost threshold in sub-regulatory guidance for determining targeted beneficiaries. The specific rationale for setting the cost threshold will determine the appropriate dollar amount.
D3	Anti-Fraud Programs	We would be interested in comments on possible requirements in the area of fraud, waste and abuse over and above the incentives operating in at risk plans.	In an effort to consolidate the requirements we moved them to subpart K at §423.504(b)(4)(vi)(H) as a component of a PDP sponsor's or MA-Organization offering a MA-PD plan's overall compliance plan. Plans will be required to add a program to combat fraud, waste and abuse in their prescription drug benefits to their compliance plans, but we will not establish specific requirements for such programs. We eliminated the mandatory self-reporting requirements that were proposed, but we expect all PDP sponsors to comply with the requirement for a comprehensive fraud and abuse plan. We will revisit this issue at a later date once organizations are more familiar with the Part D benefit program. PDP sponsors should implement effective fraud and abuse programs, consistent with industry standards, to detect problems, make referrals to CMS and/or the appropriate program integrity contractor for further investigation and follow-up, and undertake corrective action. Such

#	Topic	4068-P Provision	Final Rule Provision
			provisions are crucial to the success of the Medicare Part D program and to the millions of beneficiaries who rely on such benefits.
D4	E-Prescribing	We solicited comments on many aspects of developing and implementing e-prescribing standards.	While we included a fairly lengthy discussion of e-prescribing in the August 4 NPRM, CMS will shortly issue a separate NPRM devoted to the standards that will be used for e-prescribing and have reserved §423.159(a) and §423.159(b) of this final rule for such e-prescribing standards. Therefore, the proposals we made with respect to such standards are not being addressed in this final rule. One standard we are finalizing is the requirement that both PDP sponsors and MA organizations offering MA-PD plans have the capacity to support e-prescribing, once final standards are in effect, including any standards that are established before the drug benefit begins in 2006. We proposed such language at §423.159(a) of the August 4 NPRM. We received no comments on this proposal and are adopting it at §423.159(c) without modification.
F1	Evaluating Bids	Should we adopt the standards used by OPM in 48 CFR Chap. 16?	We have adopted most of the proposed rule in the area of bid review, negotiation and approval, but we: • Clarify that the OPM-like authority (1860D-11(d)(2)(B)) is in addition to our general authority to negotiate (1860D-11(d)(2)(A)). • Clarify that we will not be proposing additional regulations based on 48 CFR Chapter 16. • Clarify that we intend to examine profit using this authority. • Clarify in the preamble of the final rule that we do not intend to require detailed information from each and every plan. We would request additional information when appropriate. • Reiterate in the preamble of the final rule our interpretation that the bid review authority does not violate the non-interference directive.
F2	Calculations	We solicited comment on the appropriateness of all of our proposed calculations.	We will adopt all of the proposed calculations with the exception of our interpretation of the so-called 'negative premium". We will allow for a "negative premium" for plans with bids below the benchmark in excess of the base beneficiary premium. This results in raising the direct subsidy of such a plan to the same level as that of all other plans.

#	Topic	4068-P Provision	Final Rule Provision
			Although the plan is supposed to be solely at risk for supplemental benefits, using the additional funds to finance additional Part D (supplemental) benefits is least problematic way to handle the additional funds because the supplemental benefits can be appropriately tracked and eliminated from the calculation of risk sharing regardless of plan performance. This would require allowing a "renegotiation" of the plan's benefit package once the national average bid and the negative premium were known. The negative premium would be reflected in the resubmitted benefit package as either a reduction in the existing supplemental premium or as the addition of new supplemental benefits for which there would be no additional enrollee premium. Any marginal effects in the basic bid (for the utilization effects of supplemental benefits) would be negotiated by OACT at the same time.
G1	Data Submission	What should be the content, format and frequency of data submissions?	Because of the complexity of the MMA payment provisions, collecting 100 percent events data is necessary. While the volume is large, the minimal number of data elements we expect to collect (<25) and the simplicity of our own data processing system should minimize the burden of this approach. Prior to making final decisions, we will discuss the draft list of selected data elements with industry including PBMs, AHIP, the NACDS, and the AMCB. Final regulatory language will provide administrative flexibility for CMS to continue developing and refining data requirements over time. Our goal will be to collect the minimum amount of data we need to perform our payment functions.
G2	Risk Adjustment	How should the drug risk adjustment account for low-income subsidy (LIS) individual utilization? Have we correctly interpreted risk adjustment budget neutrality?	Work continues internally with the assistance of contractors and the American Academy of Actuaries to develop the best possible drug risk adjustment model based initially on the relationship of drug spending to medical diagnoses. Attention is also being given to appropriate risk adjustment for low-income and institutionalized beneficiaries.
G3	Payment Adjustments	We solicited comment on many operational aspects of payment of reinsurance and low-income subsidies, as well as for risk corridors and reconciliations.	Details on proposed payment methodologies have been released in draft form for public comment. Final methodologies will be issued in separate guidance.
I1	Solvency Standards	Should our standards for financial solvency and capital adequacy for PDPs in States that do not have licensing requirements for PDPs be issued as interpretive guidance? How should solvency standards be developed for organizations without experience as, or not structured as risk-bearing entities?	Draft solvency standards have been released in draft form for public comment. Final standards will be issued in separate guidance.

#	Topic	4068-P Provision	Final Rule Provision
J1	Waivers	We solicited comments on the nature of waivers that might be required for MA plans and employer-sponsored plans, among others.	Information on waivers will not be addressed in regulation, but will be described in separate guidance.
J2	COB with Other Plans	On what basis should Part D COB user fees be imposed on Part D plans? How we can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans?	We believe Part D plans should be responsible for the payment of user fees for the services provided by the singe point of contact contractor. . The disincentives for the other potential payers of user fees to participate in the COB process are too great considering that their participation is voluntary and that we need their cooperation to keep our costs down. CMS must issue requirements for coordination of benefits by Part D plans by July 1, 2005.
J3	Part B/D COB	Should Part D cover Part B drugs denied under Part B because the pharmacy does not have a Medicare supplier number? Are there any other circumstances under which a Part B drug denied coverage under Part B should be covered under Part D? Are automatic claims cross-over procedures feasible between Part B and Part D payers?	Based on the comments received regarding the various B/D coordination issues we described, we do not believe commenters identified any circumstances under which a drug denied coverage under Part B should automatically be covered under Part D. While it is possible that we could eventually develop automatic cross-over procedures, we believe that establishing automatic claim cross-over procedures by January 1, 2006, would be onerous given many other systems and implementation challenges that must be addressed. We therefore believe that a two-step approach is the most appropriate. Once Part D is implemented, we will get a better sense for the actual volume of Part D-covered vaccines or other drugs covered by Part D but administered by a physician and the need and most appropriate mechanisms for automatic cross-over procedures.
J4	Tracking TrOOP	Should CMS or the Part D plans be responsible for determining whether claims costs have been reimbursed by alternative coverage? What are the operational capabilities of plans to manage COB at the point of sale, particularly with respect to alternative wrap around coverage? Should reporting of third-party claims costs be mandatory or voluntary? Should we require beneficiaries to give consent for release of data held by third parties as part of their enrollment application?	In the proposed rules, we considered two options for operationalizing the data exchange related to the Part D coordination of benefits system and TROOP accounting: • Option 1: The PDPs and MA-PD plans will be solely responsible for tracking TrOOP costs. • Option 2: We will procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. While this is not a regulatory issue, we will work toward some variation on Option 2, since we believe this is the most efficient and effective way to implement the TrOOP. Given the need to share information about other payers primary or secondary to Medicare Part D, as well as to establish a process that is simple to administer and results in more

#	Topic	4068-P Provision	Final Rule Provision
		Are there any temporary or phased-in approaches to tracking TrOOP that may be necessary or advisable given the short timeframe between the final rule and program implementation? How can Part D plans receive information from beneficiaries or others regarding payment made by entities that do not participate in a centralized coordination of benefits system?	complete and accurate information, we believe a single-point-of-contact (SPOC) approach best meets these objectives since it leverages existing processes and consolidates the process in a single entity, creating efficiencies of scale.
K1	Mandatory Self-Reporting	We solicited comments on our proposal to require Part D plan sponsors to report misconduct it believes may violate various criminal , civil or administrative authorities.	In response to these comments, we are eliminating from this regulation an explicit requirement that PDP sponsors report to CMS violations of law, regulation, or other wrongdoing on the part of the organization or its employees/officers. While we are not requiring PDP sponsors to engage in mandatory self-reporting, we continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan; and we strongly encourage PDP sponsors to alert CMS, the OIG, or law enforcement of any potential fraud or misconduct relating to the Part D program. Plans that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. If after reasonable inquiry, the PDP sponsor has determined that the misconduct has violated or may violate criminal, civil or administrative law, the PDP sponsor should report the existence of the misconduct to the appropriate Government authority within a reasonable period, i.e., within 60 days after the determination that a violation may have occurred. In the future, we will examine mandatory self-reporting of health care fraud and abuse across all Medicare providers and contractors.
K2	Record Retention	We proposed requiring record maintenance and retention for six years—mirroring the Medicare Advantage regulations. However, a commenter suggested that our records retention policy parallel the statute of limitations that applies to False Claims Act that is, a maximum of 10 years from the time of the violation.	Retention requirements will follow the statute of limitations that applies to the False Claims Act. As a result, in the final rule at §423.505(e)(4), we are requiring that records be maintained for 10 years from the last contracting period or audit, whichever is latest, to conform to the statute of limitations for the discovery of violations under the False Claims Act. We recognize that 10 years is the upper limit under the False Claims Act, but we believe that this period will best enable us to have access to pertinent records should this be necessary. In order to

#	Topic	4068-P Provision	Final Rule Provision
			maintain uniformity between requirements for MA organizations and other Part D sponsors, we are making a similar change to the final MA regulations.
K3	Contract Determination and bid process	We solicited comments on ways to make contract applications for entites interested in becoming Part D plan sponsors not unduly burdensome and wherever possible parallel to contract requirements for MA plans. We received comments asking us to streamline application process in a way that that does not increase administrative burden for MA plan applicants	Commenters were correct:-if contract and bid determination processes, occurred consecutively their would not leave enough time for plans to be ready for business by January 2006. Therefore we are permitting the contract determination process to run concurrently with the bid application process. Additionally, we have required that applicants receiving an intent to deny notice be given 10 days to respond instead of thirty days. These changes have all been made to MA contract requirements under Title II subpart K.
M1	Appeals	We solicited comments on our proposed rules, and I particular for coverage determinations and notices and exceptions procedures. Formulary Exceptions Procedures: We proposed a limited number of elements that must be included in a sponsor's exceptions criteria. We also considered including a number of other exceptions criteria and adding criteria for the review process that is used to evaluate formularies and tier structures Should CMS specify the decision criteria for beneficiary appeals, or should PDPs be held accountable to follow their own decision criteria? These issues are particularly critical given two key statutory requirements: 1) the enrollment "lock-in" provision, and 2) the ability of plans to make mid-year formulary changes. We need to balance enrollee protection concerns with PDP ability to obtain drug discounts.	Consistent with NPRM, we specify that coverage determination is made at the sponsor level, not at the pharmacy, and we address notice and timing issues in other ways. Rather than requiring patient-specific notices, we require that participating pharmacies either post or deliver a standardized notice that directs enrollees to contact their plan or 1-800-MEDICARE if they cannot obtain a prescribed drug or disagree with the pricing. We have shortened the coverage determination timeframe for expedited cases and the process for standard service cases. We limit tiering exceptions to obtaining a non-preferred drug at the price of a preferred drug (i.e., tier 3 down to tier 2). This is consistent with the MMA language but has been clarified. Rather than attempt to develop specific exceptions criteria (e.g., prior use requirements), we provided general guidance on issues that needed to be addressed in the exceptions criteria and proposed that sponsors establish specific criteria within those guidelines, subject to CMS review. We recommend that we generally maintain proposed approach, but adopt common State standard that failure to make a coverage determination or redetermination within the required timeframe (after physician documentation is received) constitutes a favorable decision for the enrollee.
M2	Employer Sponsored Prescription	In some instances, employers, through a group plan or otherwise, may provide prescription drug benefits in addition to those covered under Parts C and D. It is	After reviewing the public comment and conferring with representatives of DOL, we have concluded that changes (not only to the CMS regulations but also to the DOL regulations) are needed to properly

#	Topic	4068-P Provision	Final Rule Provision
	Drug Programs and Appeals	therefore possible that claims arising under such circumstances could be governed both ERISA and part 423 of our proposed regulations. As a result, we solicited comments on whether, and to what extent, the application of parallel procedures between employer sponsored prescription drug plans governed by ERISA and plans offered under part 423 of our proposed regulations might be a problem for plans, employers, and/or eligible individuals. We also solicited suggestions for addressing problems, if any, that result from the application of parallel procedures.	address this issue. Accordingly, we have added § 423.562(d), which is intended to give ERISA plans the option, pursuant to regulations of the Secretary of Labor, of electing the Part D process rather than the procedures under 29 CFR 2560.503-1 for claims involving supplemental benefits provided by contract with a Part D plan. In this regard, DOL has agreed to work with CMS to develop such regulations. We note that the language in § 423.562(d) is intended to demonstrate our commitment to make the entire Part D process available in this context. The provision in § 423.562(d) would not take effect in the absence of regulations by the Secretary of Labor.
N1	Contract Determinations and Appeals	Commenters believed that our application and determination process under the present timelines would not allow sufficient time for Part D plans to be prepared for enrollment by the November 15 date.	We have made July 15th the cut-off date for contract determinations for organizations wishing to provide coverage in the next calendar year. This change has also been made to Title II subpart N, as well.
P1	Low-Income Subsidy Determinations and Notification	Eligibility determinations, redeterminations and appeal process for low-income subsidies: We are considering a number of options to ease the burden on States and to ensure, to the degree permissible under the MMA, a consistent eligibility process. We invite general comments on how we can ensure a consistent eligibility determination process. Sliding Scale Premium: How should we calculate the sliding scale premium subsidy for individuals with income from 135 percent up to 150 percent of the FPL? We offer an example to set a scale in a stepped fashion, for example, a set decrease in the subsidy amount for every 5 percent increase in income level.	The final regulation requires that low-income subsidy eligibilty determinations must be determined by either the SSA or the State Medicaid Agency in accordance with the statute. However, in response to comments, we strongly encourage states to use the SSA process by aiding individuals with the SSA application process, and submitting applications to SSA on their behalf. However, if an individual specifically requests a state determination the state must have the ability to determine low-income subsidy eligibility. To relieve the burden on states, CMS will not require states to inform beneficiaries of the deemed subsidy eligibles in the final rule. CMS will send notices to all deemed eligibles. We have adopted into final regulation the sliding scale premium calculation as it was set forth in the preamble of the proposed regulation.
P2	Reimbursement of Cost-Sharing Subsidy	Reimbursement for cost sharing paid before notification of eligibility for low-income subsidy: We are requesting comments on how to best reimburse subsidy eligible individuals with respect to out-of-pocket costs for premiums and cost-sharing incurred before the date the individual was notified of subsidy eligibility, but after the effective date the individual became subsidy eligible. Reimbursement for cost sharing paid by charities or other programs: Similarly, we are requesting comments on how	We require that the Part D plan be responsible for direct reimbursement to beneficiaries for out-of-pocket costs incurred after the effective date of subsidy eligibility. We also require the Part D plan to have processes for reimbursing a charity or program for any premium and cost sharing amounts paid on

#	Topic	4068-P Provision	Final Rule Provision
		to deal with premiums and cost sharing paid by charities or other programs, for example, the Ryan White program or State Pharmacy Assistance programs, on behalf of an individual during a period when he or she is determined to be subsidy eligible.	behalf of an individual subsequent to the effective date of the subsidy. This would eliminate the need for reimbursement to be made by CMS or the individual him or herself.
Q1	Fallback Plan Requirements	Definition of Offering a Fallback Plan / Fallback Plan Contract Type: Should we define "offering a fallback plan" as agreeing to potentially offer a plan in a region, or as actually providing a fallback plan in fallback service areas? Should we use the Indefinite Delivery type of contract?	We adopted the interpretation that offering a fallback plan means actually providing a fallback plan in fallback service areas, This furthers the goal of facilitating competition by allowing former fallback contractors to enter the risk bidding a year sooner (assuming they did not actually provide a fallback plan in year 3 of the contract cycle). We have determined that fallback contracts will not be written under the FAR or 48 CFR provisions, therefore it is no longer accurate to refer to the standby contracts as indefinite duration, indefinite quantity (IDIQ) contracts -- which is a term used under the FAR. Nonetheless, we expect to have umbrella provisions, which provide the necessary flexibility to deploy a fallback plan during a contract year in the event of a risk plan failure. Although the fallback contracts will not be written in accordance with the provisions of the FAR or 48 CFR, and will not look like typical "FAR contracts," as we stated in the NPRM at 69 Fed. Reg.46734, we will enter into fallback contracts using the federal acquisition rules on a timetable to ensure that the contracts are in place on time (i.e., at the same time as the risk plans would otherwise be offered).
Q2	Fallback Payment	Fallback Payment Process: We request comment on fallback payment methodologies, particularly in regard to prospective or retrospective rebate allocation. Price Reference Points Other Than AWP: We would also like to receive comments on alternative reference points or alternative methodologies that could promote competitive pricing.	Information on the fallback payment process will not be addressed in regulation, but will be described in separate guidance. Despite its frequent fluctuations and inherent vulnerability to manipulation, the AWP remains the primary measuring stick for drug costs. We will therefore be incorporating it into our performance targets, but we will also be looking at other indicators or proxies for financial performance, such as rates of generic substitution, that will provide other perspectives on cost management.
Q3	Fallback Premiums	In the NPRM we stated: "Premiums from beneficiaries enrolled in fallback plans would not be collected by the plan. Instead, these premiums would be withheld from social security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not	We have clarified that we have the authority to require that premiums be collected by fallback plans, and to deduct such amounts from payments due to fallback plans in the case of any individual who does not receive such benefits or annuities, or who receives insufficient benefits or annuities to cover the monthly premium. We believe this procedure is

#	Topic	4068-P Provision	Final Rule Provision
		receive social security checks or otherwise have premiums deducted from other benefits or annuities would pay us directly." Can fallback plans collect beneficiary premiums that are not withheld by SSA, or must these be collected by CMS?	more familiar to beneficiaries and to plans, and allows the plan to be in closer touch with the beneficiary's enrollment status. Therefore, we have modified § 423.867(b) to reflect this clarification.
Q4	Access Standards in the Territories	Waivers for Plans in Territories: Are the waivers proposed for the territories appropriate? Are any others warranted to ensure access to individuals residing in the territories?	The only comments received with respect to the territories concerned the design of the regions, and these have been addressed in separate guidance. As a result, CMS has retained the broad waiver authority in § 423.859(c) without modification, and will continue to conduct research to determine how best to facilitate Part D coverage in the territories. Specific waivers will be addressed in separate guidance.
R2	Subsidy Process	We solicited comments on many aspects of the proposed retiree drug subsidy process.	Most details of the subsidy operational process, including specifics on cost data, will be issued in separate guidance. However, we did: • Announce that we would allow retiree drug plans the flexibility to receive subsidy payments on a monthly, quarterly or annual basis at their discretion; and • Clarify the information that must be submitted with enrollment data.
R3	Actuarial Equivalence for Subsidy	Approaches to Net Test: Can we clarify the likely responses of plan sponsors to these different approaches? In addition, we solicit comments not only on the desirability of the different options, but also on the legal bases for possible options.	To qualify for the subsidy, a plan sponsor must show that its coverage is "actuarially equivalent" to (*i.e.*, at least as generous as) the new Part D standard drug benefit. The final regulation includes a two-part test for plan sponsors to determine whether this standard, referred to as "actuarial equivalence," has been met.
T1	Change in Definition of Outpatient Prescription Drugs	We solicit comments on the new definition for purposes of the physician self-referral prohibition.	We have finalized this proposal without substantive change because we believe that referrals for Part D drugs are subject to the same risk of overutilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs.
T2	Waivers Needed for Cost Plans or CMPs	We invite comment on whether there are any Part D requirements otherwise applicable to MA-PD plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs.	We have clarified that Part D will be offered somewhat differently by cost plans. (1) Cost plans that choose to offer qualified Part D coverage under §417.440(b)(2) may do so only by offering qualified Part D coverage as an optional supplemental benefit. (2) Cost plans that offer qualified Part D coverage must offer basic

#	Topic	4068-P Provision	Final Rule Provision
			prescription drug coverage. A cost plan that offers basic prescription drug coverage may offer additional qualified Part D coverage choices. (3) A cost plan that does not offer qualified Part D coverage under 417.440(b)(2) may offer non-qualified drug coverage that is not reimbursed under this Part or Title. Information on waivers will not be addressed in regulation, but will be described in separate guidance.
T3	Creditable Coverage Notice for Medigap Policies	The proposed rule sets forth a draft disclosure notice for Medigap issuers to use for policies that do not have creditable coverage. We solicited comments on how the draft disclosure notice could be adapted for the types of Medigap policies that do provide creditable coverage.	We have determined that the format and content of the notice could be improved based on information gathered through consumer testing, so we now plan to publish the final model disclosure notice separately from this final regulation. We also plan to publish a model disclosure notice for policies that do provide creditable coverage.
T4	PACE Waivers	We invite comments on the MMA requirements we have proposed to be waived for PACE organizations and ask for comment on additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.	Information on waivers will not be addressed in regulation, but will be described in separate guidance. We will make a payment adjustment to PACE organizations on behalf of Part D dual eligible enrollees to account for any discrepancy between a PACE organization's bid and the low-income premium subsidy amount in its region, as well as the predicted cost of nominal co-payment amounts. We would exercise our authority under section 1894(d)(2) of the Act and section 460.180(b)(5) of the PACE regulation in making this Medicare Part D adjustment to PACE organizations to account for "other factors" determined to be appropriate. This Part D payment methodology for PACE organizations would be outlined in additional CMS guidelines to PACE organizations following the publication of CMS 4068-F and would take into account the unique statutory preclusions against enrollee cost-sharing and regulatory preclusion against charging premiums to Medicaid eligible enrollees.